

FORM PTO-1595

(Rev. 3-01)

OMB No. 0651-0027 (exp. 5/31/2002)

RECORDATION FORM SHEET COVER

PATENTS ONLY

U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office

To the Honorable Commissioner of Patent and Trademarks: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):

Beth A. Burnside
Xiaoxi Guo
Kimberly Fiske
Richard A. Couch
Donald J. Treacy
Rong-Kun Chang
Charlotte M. McGuinness
Edward M. Rudnic

Additional name(s) of conveying party(ies) attached:

☐ Yes ☒ No

2. Name and address of receiving party(ies):

Name: Shire Laboratories, Inc.

Internal Address:

Street Address: 1550 East Gude DriveCity: RockvilleState: MarylandZip: 20850

3. Nature of conveyance:

- ☒ Assignment ☐ Merger
☐ Security/Agreement ☐ Change of Name
☐ Other

Execution Date: 6/25/01, 7/10/01, 7/12/01, 7/2/01, 6/5/01,
7/3/01, 6/22/01 and 6/4/01

Additional name(s) & address(es) attached: ☐ Yes ☒ No4. Application number(s) or patent number(s): 09/807,462

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No.(s)

B. Patent No.(s)

Additional numbers attached? ☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Raymond J. LillieInternal Address: Carella, Byrne, Bain, Gilfillan, Cecchi,
Stewart & OlsteinStreet Address: 6 Becker Farm RoadCity: Roseland State: New Jersey Zip: 070686. Total number of applications and patents involved: 17. Total fee (37 CFR 3.41)....\$40.00☒ Enclosed☒ Additional fees, if any, authorized to be charged to deposit account8. Deposit account number: 03-0678

(Attach duplicate copy of this page if paying by deposit account)

DO NOT USE THIS SPACE

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Raymond J. Lillie
Name of Person Signing

Raymond J. Lillie
Signature

July 19, 2001
Date

Total number of pages including cover sheet, attachments, and document: 4

Mail documents to be recorded with required cover sheet information to:
Commissioner of Patents & Trademarks, Box Assignments
Washington, D.C. 20231

ASSIGNMENT

For good and valuable consideration, the receipt of which is hereby acknowledged, the undersigned Beth A. Burnside, 1808 Briggs Chaney Road, Silver Spring, Maryland 20905, Xiaodi Guo, 7201 Dubuque Court, Derwood, Maryland 20855, Kimberly Flske, 7479 Hickory Log Circle, Columbia, Maryland 21045, Richard A. Couch, 7620 Old Georgetown Road, Apt. 1021, Bethesda Maryland 20814, Donald J. Treacy, 1335 Farley Court, Arnold, Maryland 21012, Rong-Kun Chang, 306 Springbrook Court, Hockessin, Delaware 19707, Charlotte M. McGuinness, 6510 Broxborn Drive, Bethesda, Maryland 20817 and Edward M. Rudnic, 15103 Gravenstein Way, North Potomac, Maryland 20878 hereby sells, assigns and transfers to Shire Laboratories, Inc., incorporated ("Assignee") having a place of business at 1550 East Gude Drive, Rockville, Maryland 20850, a Maryland Corporation, its successors, assigns and legal representatives, his entire right, title and interest for the United States and all other countries, in and to the improvements(s) known as United States Application Serial No. 09/807,462, filed April 11, 2001, and/or executed on even date herewith and is entitled:

ORAL PULSED DOSE DRUG DELIVERY SYSTEM

and in and to said application and all divisional, continuing, substitute, renewal, reissue and all other applications for Letters Patent which have been or shall be filed in the United States and all other countries on any of said improvements, and in and to all original and reissued patents which have been or shall be issued in the United States and all other countries on said improvements (hereinafter collectively, the "Improvements").

The undersigned further agrees that said Assignee may apply for and receive Letters Patent for said Improvements in its own name; and, when requested, without charge to but at the expense of Assignee, its successors, assigns and legal representatives, to carry out in good faith the intent and purpose of this assignment, the undersigned will execute all divisional, continuing, substitute, renewal, reissue and all other patent applications on all such Improvements; execute all rightful oaths, assignments, powers of attorney and other papers; communicate to said Assignee, its successors, assigns and representatives all facts known to the undersigned relating to said Improvements and the history thereof; and do everything possible which said Assignee, its successors, assigns or representatives shall consider desirable for aiding in securing and maintaining proper patent protection for said Improvements and for vesting title to said Improvements and all applications for patent and all patents on said improvements in Assignee, its successors, assigns and representatives.

The undersigned hereby represents and warrants to Assignee, its successors, assigns and representatives that no assignment, grant, mortgage, license or other right or agreement affecting the rights and property herein conveyed has been made to others by the undersigned and that full right to convey the same as expressed herein is possessed by the undersigned.

The undersigned hereby grants power to Alan J. Grant (Reg. No. 33,389), John G. Gilfillan, III (Reg. No. 22,746); Elliot M. Olstein (Reg. No. 24,025); Raymond J. Lillie (Reg. No. 31,778); William Squire (Reg. No. 25,378); and John N. Bain (Reg. No. 18,651) to insert on this Assignment any further identification which may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office for recordation of this document. Address correspondence and telephone calls to Raymond J. Lillie c/o of Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein, 6 Becker Farm Road, Roseland, New Jersey 07068

IN WITNESS WHEREOF, this Assignment is executed by the undersigned on the date(s) opposite their signature(s):

Inventor's Signature: Beth A. Burnside Date: 25 Jun 01
Beth A. Burnside

STATE OF MD . COUNTY OF Montgomery ss.:

Before me this 25th day of June, 2001, personally appeared the above named individual(s), to me known to be the person(s) who are described in and who executed the foregoing assignment instrument and acknowledged to me that they executed the same of their own free will for the purpose therein expressed.

Marcy Fandler Blackberry
Notary Public

Inventor's Signature: Xiaodi Guo Date: 10-July-01
Xiaodi Guo

STATE OF MD . COUNTY OF Montgomery ss.:

Before me this 10th day of July, 2001, personally appeared the above named individual(s), to me known to be the person(s) who are described in and who executed the foregoing assignment instrument and acknowledged to me that they executed the same of their own free will for the purpose therein expressed.

Marcy Fandler Blackberry
Notary Public

Inventor's Signature: Kimberly Fiske

Kimberly Fiske

Date: 125 Jun 01STATE OF MD , COUNTY OF Montgomery SS.:

Before me this 12th day of July, 2001, personally appeared the above named individual(s), to me known to be the person(s) who are described in and who executed the foregoing assignment instrument and acknowledged to me that they executed the same of their own free will for the purpose therein expressed.

Nancy Fausler Blackberg
Notary Public

Inventor's Signature: Richard A. Couch

Richard A. Couch

Date: 02-JUL-01STATE OF MD , COUNTY OF Montgomery SS.:

Before me this 2nd day of July, 2001, personally appeared the above named individual(s), to me known to be the person(s) who are described in and who executed the foregoing assignment instrument and acknowledged to me that they executed the same of their own free will for the purpose therein expressed.

Nancy Fausler Blackberg
Notary Public

Inventor's Signature: Donald J. Treacy

Donald J. Treacy

Date: 05 JUNE 01STATE OF MD , COUNTY OF MONTGOMERY SS.:

Before me this 5th day of June, 2001, personally appeared the above named individual(s), to me known to be the person(s) who are described in and who executed the foregoing assignment instrument and acknowledged to me that they executed the same of their own free will for the purpose therein expressed.

Julie M. Clifford
Notary Public

Julie M. Clifford, Notary Public
Montgomery County
State of Maryland
My Commission Expires Feb. 1, 2003

Inventor's Signature: Rong-Kun Chang

Rong-Kun Chang

Date: 7/3/01STATE OF MD , COUNTY OF Montgomery SS.:

Before me this 3rd day of July, 2001, personally appeared the above named individual(s), to me known to be the person(s) who are described in and who executed the foregoing assignment instrument and acknowledged to me that they executed the same of their own free will for the purpose therein expressed.

Nancy Fausler Blackberg
Notary Public

Full name of third joint inventor: Kimberly FiskeInventor's signature: *Kimberly Fiske* Date: 11 Jul 01
Residence: 4858 W Braddock Rd #20 Alexandria, VA 22311
7479 Hickory Log Circle, Columbia, Maryland 21045 Citizenship: USA
Post Office Address: same 18 11 Jul 01Full name of fourth joint inventor: Richard A. CouchInventor's signature: *Richard A. Couch* Date: 02-JUL-01
Residence: 7620 Old Georgetown Road, Apt. 1021, Bethesda Maryland 20814 Citizenship: USA
Post Office Address: sameFull name of fifth joint inventor: Donald J. TreacyInventor's signature: *Donald J. Treacy* Date: 05 JUNE 01
Residence: 1335 Farley Court, Annapolis, Maryland 21012 Citizenship: USA
Post Office Address: sameFull name of sixth joint inventor: Rong-Kun ChangInventor's signature: *Rong-Kun Chang* Date: 7/3/01
Residence: 306 Springbrook Court, Hockessin, Delaware 19707 Citizenship: USA
Post Office Address: sameFull name of seventh joint inventor: Charlotte M. McGuinnessInventor's signature: *Charlotte M. McGuinness* Date: 18 June 01
Residence: 6510 Broxborn Drive, Bethesda, Maryland 20817 Citizenship: USA
Post Office Address: sameFull name of eighth joint inventor: Edward M. RudnicInventor's signature: *Edward M. Rudnic* Date: 6/4/01
Residence: 15103 Gravenstein Way, North Potomac, Maryland 20878 Citizenship: USA
Post Office Address: same

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

ORAL PULSED DOSE DRUG DELIVERY SYSTEM

the specification of which [] is attached hereto or [X] was filed on April 11, 2001 as Application Serial No. 09/807,462

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed. Prior Foreign Application(s):

Priority Claimed	
Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

(Number)	(Country)	(Day/Month/Year Filed)
I hereby claim the benefit under Title 35, United States Code, Section(s) 119 and/or 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:		

PCI/US99/24554
(Application Serial No.)

20 October 1999
(Filing Date)

Abandoned
(Status)

US 09/176,542
(Application Serial No.)

21 October 1998
(Filing Date)

Pending
(Status)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: John N. Bain (Reg. No. 18,651); John G. Gilfillan, III (Reg. No. 22,746); Elliot M. Olstein (Reg. No. 24,025); Raymond J. Lillie (Reg. No. 31,778); William Squire (Reg. No. 25,378); and Alan J. Grant (Reg. No. 33,389). Address correspondence and telephone calls to:

Raymond J. Lillie, Esq. c/o Carella, Byrne, Bain, Gilfillan, Cocchi, Stewart & Olstein, 6 Becker Farm Road, Roseland, NJ 07068 - (973) 994-1700.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor: Beth A. Burnside

Inventor's signature: Beth A. Burnside Date: 25 Jun 01

Residence: 1808 Briggs Chaney Road, Silver Spring, Maryland 20905 Citizenship: U.S.A.

Post Office Address: same

Full name of second joint inventor: Xiaodi Guo

Inventor's signature: Xiaodi Guo Date: 10 July 01

Residence: 7201 Dubuque Court, Derwood, Maryland 20855 Citizenship: USA

Post Office Address: same

FORM PTO-1595

(Rev. 3-01)

OMB No. 0651-0027 (exp. 5/31/2002)

RECORDATION FORM SHEET COVER PATENTS ONLY

U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office

To the Honorable Commissioner of Patent and Trademarks: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies).

Beth A. Burnside
Xiaoxi Guo
Kimberly Fiske
Richard A. Couch
Donald J. Treacy
Rong-Kun Chang
Charlotte M. McGuinness
Edward M. Rudnic

Additional name(s) of conveying party(ies) attached:

☐ Yes ☒ No

3. Nature of conveyance:

- ☒ Assignment ☐ Merger
☐ Security/Agreement ☐ Change of Name
☐ Other

Execution Date: 6/25/01, 7/10/01, 7/12/01, 7/2/01, 6/5/01,
7/3/01, 6/22/01 and 6/4/01

2. Name and address of receiving party(ies):

Name: Shire Laboratories, Inc.

Internal Address:

Street Address: 1550 East Gude DriveCity: RockvilleState: MarylandZip: 20850Additional name(s) & address(es) attached: ☐ Yes ☒ No4. Application number(s) or patent number(s): 09/807,462

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No.(s)

B. Patent No.(s)

Additional numbers attached? ☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Raymond J. LillieInternal Address: Carella, Byrne, Bain, Gilfillan, Cecchi,
Stewart & OlssteinStreet Address: 6 Becker Farm RoadCity: Roseland State: New Jersey Zip: 070686. Total number of applications and patents involved: 17. Total fee (37 CFR 3.41)...\$40.00☒ Enclosed☒ Additional fees, if any, authorized to be charged to deposit account8. Deposit account number: 03-0678

(Attach duplicate copy of this page if paying by deposit account)

DO NOT USE THIS SPACE

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document

Raymond J. Lillie

Name of Person Signing



Signature

July 19, 2001

Date

Total number of pages including cover sheet, attachments, and document: 4

ASSIGNMENT

For good and valuable consideration, the receipt of which is hereby acknowledged, the undersigned Beth A. Burnside, 1808 Briggs Chaney Road, Silver Spring, Maryland 20905, Xiaodi Guo, 7201 Dubuque Court, Derwood, Maryland 20855, Kimberly Fiske, 7479 Hickory Log Circle, Columbia, Maryland 21045, Richard A. Couch, 7620 Old Georgetown Road, Apt. 1021, Bethesda Maryland 20814, Donald J. Treacy, 1335 Farley Court, Arnold, Maryland 21012, Rong-Kun Chang, 306 Springbrook Court, Hockessin, Delaware 19707, Charlotte M. McGuinness, 6510 Broxborn Drive, Bethesda, Maryland 20817 and Edward M. Rudnic, 15103 Cravenstein Way, North Potomac, Maryland 20878 hereby sells, assigns and transfers to Shire Laboratories, Inc., incorporated ("Assignee") having a place of business at 1550 East Gude Drive, Rockville, Maryland 20850, a Maryland Corporation, its successors, assigns and legal representatives, his entire right, title and interest for the United States and all other countries, in and to the improvement(s) known as United States Application Serial No. 09/807,462, filed April 11, 2001, and/or executed on even date herewith and is entitled:

ORAL PULSED DOSE DRUG DELIVERY SYSTEM

and in and to said application and all divisional, continuing, substitute, renewal, reissue and all other applications for Letters Patent which have been or shall be filed in the United States and all other countries on any of said improvements, and in and to all original and reissued patents which have been or shall be issued in the United States and all other countries on said improvements (hereinafter collectively, the "Improvements").

The undersigned further agrees that said Assignee may apply for and receive Letters Patent for said Improvements in its own name; and, when requested, without charge to but at the expense of Assignee, its successors, assigns and legal representatives, to carry out in good faith the intent and purpose of this assignment, the undersigned will execute all divisional, continuing, substitute, renewal, reissue and all other patent applications on all such Improvements; execute all rightful oaths, assignments, powers of attorney and other papers; communicate to said Assignee, its successors, assigns and representatives all facts known to the undersigned relating to said Improvements and the history thereof; and do everything possible which said Assignee, its successors, assigns or representatives shall consider desirable for aiding in securing and maintaining proper patent protection for said Improvements and for vesting title to said Improvements and all applications for patent and all patents on said improvements in Assignee, its successors, assigns and representatives.

The undersigned hereby represents and warrants to Assignee, its successors, assigns and representatives that no assignment, grant, mortgage, license or other right or agreement affecting the rights and property herein conveyed has been made to others by the undersigned and that full right to convey the same as expressed herein is possessed by the undersigned.

The undersigned hereby grants power to Alan J. Grant (Reg. No. 33,389), John G. Gilfillan, III (Reg. No. 22,746); Elliot M. Olstein (Reg. No. 24,025); Raymond J. Lillie (Reg. No. 31,778); William Squire (Reg. No. 25,378); and John N. Bain (Reg. No. 18,651) to insert on this Assignment any further identification which may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office for recordation of this document. Address correspondence and telephone calls to Raymond J. Lillie c/o of Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein, 6 Becker Farm Road, Roseland, New Jersey 07068

IN WITNESS WHEREOF, this Assignment is executed by the undersigned on the date(s) opposite their signature(s):

Inventor's Signature: Beth A. Burnside Date: 25 Jun 01
Beth A. Burnside

STATE OF MD, COUNTY OF Montgomery SS.:

Before me this 25th day of June, 2001, personally appeared the above named individual(s), to me known to be the person(s) who are described in and who executed the foregoing assignment instrument and acknowledged to me that they executed the same of their own free will for the purpose therein expressed.

Marcy Fandler Blackberg
Notary Public

Inventor's Signature: Xiaodi Guo Date: 10 July 01
Xiaodi Guo

STATE OF MD, COUNTY OF Montgomery SS.:

Before me this 10th day of July, 2001, personally appeared the above named individual(s), to me known to be the person(s) who are described in and who executed the foregoing assignment instrument and acknowledged to me that they executed the same of their own free will for the purpose therein expressed.

Marcy Fandler Blackberg
Notary Public

Inventor's Signature: Charlotte M. McGuinnessDate: 22 June 01

Charlotte M. McGuinness

DISTRICT OF COLUMBIA

STATE OF _____, COUNTY OF _____ SS.:

Before me this 22nd day of June, 2001, personally appeared the above named individual(s), to me known to be the person(s) who are described in and who executed the foregoing assignment instrument and acknowledged to me that they executed the same of their own free will for the purpose therein expressed

Carol B. Friend
Notary Public

My Commission Exps. October 14, 2001

Inventor's Signature: Edward M. RudnicDate: 6/4/01

Edward M. Rudnic

STATE OF MD, COUNTY OF MONTGOMERY

Before me this 4th day of June, 2001, personally appeared the above named individual(s), to me known to be the person(s) who are described in and who executed the foregoing assignment instrument and acknowledged to me that they executed the same of their own free will for the purpose therein expressed

Julie M. Clifford
Notary Public

Julie M. Clifford, Notary Public
Montgomery County
State of Maryland

My Commission Expires Feb. 1, 2003

CARELLA, BYRNE, BAIN, GILFILLAN, CECCHI, STEWART & OLSTEIN
6 Becker Farm Road - Roseland, NJ 07068 - (973) 994-1700

Docket No. 550750-185
#102358 v1

Inventor's Signature:

Kimberly Fiske

Date:

12 July 01

STATE OF MD, COUNTY OF Montgomery SS.:

Before me this 12th day of July, 2001, personally appeared the above named individual(s), to me known to be the person(s) who are described in and who executed the foregoing assignment instrument and acknowledged to me that they executed the same of their own free will for the purpose therein expressed.

Nancy Fowler Blackshear
Notary Public

Inventor's Signature:

Richard A. Couch

Date:

02-JUL-01

STATE OF MD, COUNTY OF Montgomery SS.:

Before me this 2nd day of July, 2001, personally appeared the above named individual(s), to me known to be the person(s) who are described in and who executed the foregoing assignment instrument and acknowledged to me that they executed the same of their own free will for the purpose therein expressed.

Nancy Fowler Blackshear
Notary Public

Inventor's Signature:

Donald J. Treacy

Date:

25-June-01

STATE OF MD, COUNTY OF MONTGOMERY SS.:

Before me this 5th day of June, 2001, personally appeared the above named individual(s), to me known to be the person(s) who are described in and who executed the foregoing assignment instrument and acknowledged to me that they executed the same of their own free will for the purpose therein expressed.

Julie M. Clifford
Notary Public

Julie M. Clifford, Notary Public
Montgomery County
State of Maryland
My Commission Expires Feb. 1, 2003

Inventor's Signature:

Rong-Kun Chang

Date:

7/3/01

STATE OF MD, COUNTY OF Montgomery SS.:

Before me this 3rd day of July, 2001, personally appeared the above named individual(s), to me known to be the person(s) who are described in and who executed the foregoing assignment instrument and acknowledged to me that they executed the same of their own free will for the purpose therein expressed.

Nancy Fowler Blackshear
Notary Public

Full name of third joint inventor: Kimberly FiskeInventor's signature: Kimberly Fiske Date: 11 Jul 01Residence: 4858 W Braddock Rd #20 Alexandria, VA 223117479 Hickory Log Circle, Columbia, Maryland 21045Citizenship: USAPost Office Address: same

VA 28 11 Jul 01

Full name of fourth joint inventor: Richard A. CouchInventor's signature: Richard A. Couch Date: 02-JUL-01Residence: 7620 Old Georgetown Road, Apt. 1021, Bethesda Maryland 20814Citizenship: USAPost Office Address: same

MD

Full name of fifth joint inventor: Donald J. TracyInventor's signature: Donald J. Tracy Date: 05 JUL 01Residence: 1335 Farley Court, Annapolis, Maryland 21012Citizenship: USAPost Office Address: same

MD

Full name of sixth joint inventor: Rong-Kun ChangInventor's signature: Rong-Kun Chang Date: 7/13/01Residence: 306 Springbrook Court, Hockessin, Delaware 19707Citizenship: USAPost Office Address: same

DE

Full name of seventh joint inventor: Charlotte M. McGuinnessInventor's signature: Charlotte M. McGuinness Date: 18 June 01Residence: 6510 Broxborn Drive, Bethesda, Maryland 20817Citizenship: USAPost Office Address: same

MD

Full name of eighth joint inventor: Edward M. RudnicInventor's signature: Edward M. Rudnic Date: 6/4/01Residence: 15103 Gravenstein Way, North Potomac, Maryland 20878Citizenship: USAPost Office Address: same

MD

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

ORAL PULSED DOSE DRUG DELIVERY SYSTEM

the specification of which [] is attached hereto or [X] was filed on April 11, 2001 as Application Serial No. 09/807,462

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed. Prior Foreign Application(s):

Priority Claimed

Yes	No
<input type="checkbox"/>	<input type="checkbox"/>

(Number)

(Country)

(Day/Month/Year Filed)

I hereby claim the benefit under Title 35, United States Code, Section(s) 119 and/or 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

PCT/US99/24554

20 October 1999

Abandoned

(Application Serial No.)

(Filing Date)

(Status)

US 09/176,542

21 October 1998

Pending

(Application Serial No.)

(Filing Date)

(Status)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith: John N. Bain (Reg. No. 18,651), John G. Gilfillan, III (Reg. No. 22,746), Elliot M. Olstein (Reg. No. 24,025), Raymond J. Lillie (Reg. No. 31,778), William Squire (Reg. No. 25,378), and Alan J. Grant (Reg. No. 33,389). Address correspondence and telephone calls to:

Raymond J. Lillie, Esq. c/o Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein, 6 Becker Farm Road, Roseland, NJ 07068 - (973) 994-1700.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor: Beth A. BurnsideInventor's signature: Beth A. BurnsideDate: 25 Jun 01Residence: 1808 Briggs Chaney Road, Silver Spring, Maryland 20905 Citizenship: USAPost Office Address: sameFull name of second joint inventor: Xiaoli GuoInventor's signature: Xiaoli GuoDate: 10 July 01Residence: 7201 Dubuque Court, Derwood, Maryland 20855 MD Citizenship: USAPost Office Address: same

Document2

**CARELLA, BYRNE, BAIN, GILFILLAN
CECCHI, STEWART & OLSTEIN**
6 Becker Farm Road
Roseland, New Jersey 07068
(973) 994-1700
(973) 994-1744 (FAX)

OPERATOR: LK**TIME COMPLETED:** _____**EXT. NO.:** 527**DATE:** October 1, 2001**OUR FILE NO.:** 550750-185**NAME**

Karen Williams

FIRM:

U.S. Patent and Trademark Office

FAX NO.

703-305-3230

FROM: Raymond J. Lillie**Total Pages Included Transmittal Sheet:** 14**COMMENTS:**

IF YOU HAVE ANY PROBLEMS WITH THIS TRANSMISSION, OR DO NOT RECEIVE THE NUMBER OF PAGES NOTED, PLEASE CONTACT THE FAX OPERATOR AT (973) 994-1700 (EXT. 211)

CONFIDENTIALITY NOTE: The documents accompanying this telecopy transmission contain information from the law firm of Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein, which is confidential and/or legally privileged. The information contained in this facsimile is intended only for the use of the individual named above and others who have been specifically authorized to receive it. If the one receiving it is not the intended recipient, you are hereby notified that any dissemination, distribution or copy of this communication is strictly prohibited. If you have received this telecopy in error, please notify us by telephone immediately so that we can arrange for the return of the original documents to us at once. Thank you.

The original of this document will be sent by:

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() Messenger

() Overnight Mail
(X) This will be the only form of
delivery of this Document

Please date stamp and return to addressee on reverse side

Applicant(s) Burnside, et alSerial No.: 091807,462 Filed: April 11, 2001
Title (or mark): Oral Pulsed Dose Drug Delivery
System**DOCUMENTS ENCLOSED**☐ Application sheets: Descr.: _____

Drawing sheets: _____

7/2/01, 6/25/01, 7/10/01, 7/11/01,☒ Declaration (executed 6/5/01, 7/3/01, 6/18/01,
6/4/01)☐ Verified Statement Claiming Small Entity Status☐ Response to OA dated _____☐ _____ Mo. Ext. of Time☒ Other Application Transmittal Letter:
Copy of notification of missing requirements☐ Formal Drawing _____ sheets

Claims _____ Abstract _____

☐ Formal☐ Informal☒ Assignment to Shire Laboratories, Inc☐ Type of OA: _____☐ Inform. Disc. Statement☒ Petition for Extension of time
(1 month sm enr.)☒ Check Amount \$ 160.00 No. _____

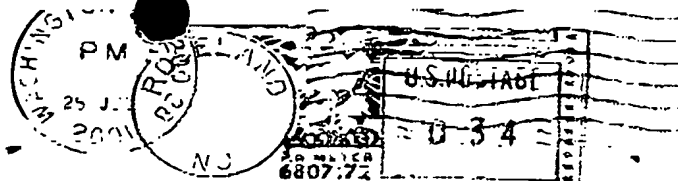
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EL680647999USDeposited on: July 19, 2001Atty.: ATL

First class mail

Certificate Dated: _____

Docket No.: 550750-185



**CARELLA, BYRNE, BAIN, GILFILLAN
CECCHI, STEWART & OLSTEIN, P.A.**

6 Becker Farm Road
Roseland, New Jersey 07068

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In: 07003		1st Day: 1st		Postage: \$1.10	
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City: NEWARK		3rd Day: 1st		COD Fee: \$0.00	
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Country: USA		5th Day: 1st		Total Postage & Fees: \$1.10	
Delivery: 1st		6th Day: 1st		Total Postage & Fees: \$1.10	
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TO: PLEASE PRINT
NAME: [Redacted]
ADDRESS: [Redacted]
CITY: [Redacted]
STATE: [Redacted]
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WARRANT OF SIGNATURE (Domestic). Only Addressee's signature is required. If delivery is to be made without delivery signature or addressee's agent (if delivery employee is required) and addressee can be left in secure location, even if delivery employee's signature constitutes valid proof of delivery.

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Carella, Byrne, Bain, Giffilan, Cerchi, Stewart & Ostein P.A.

ATTORNEY BUSINESS ACCOUNT REIMBURSEMENT ACCOUNT

CHECK DATE: 07-18-2001

CHECK NO: 5278

PAYEE: HON. COMMISSIONER OF PATENTS

CLIENT:

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Carella, Byrne, Bain, Giffilan, Cerchi, Stewart & Ostein P.A.

ATTORNEY BUSINESS ACCOUNT REIMBURSEMENT ACCOUNT

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Check No: 5278

55-2212

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EXECUTIVE OFFICE
NEWARK, NJ 07102

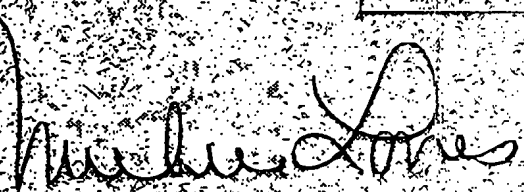
DATE: 07-18-2001

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⑈ 5278 ⑈ ⑆021200025⑆ 2011310202718⑈

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**Patent Examining Operations**

Application of: Burnside, et al.
Serial No: 09/807,462 Art Unit: Not Assigned
Filed: April 11, 2001 Examiner: Not assigned
Title: Oral Pulsed Dose Drug Delivery System
Attorney
Docket No.: 550750-185

TRANSMITTAL LETTER

Box Assignments
Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Enclosed please find the following:

1. Executed Declaration and Power of Attorney;
2. Assignment;
3. Assignment Recordation form;
4. Petition for Extension of Time (1 month small entity);
5. Copy of Notification of Missing Requirements;
6. Check No. _____ in the amount of \$ 160.00; and
7. A self-addressed, postage paid, return receipt postcard, date stamp and return of which is respectfully requested.

The Commissioner is authorized to charge payment of any additional filing fees required under 37 C.F.R. 1.16 associated with this communication or credit any overpayment to Deposit Account No. 03-0678.

FIRST CLASS CERTIFICATE

I hereby certify that this correspondence is being deposited today with the U.S. Postal Service as First Class Mail in an envelope addressed to: Box Assignment
Assistant Commissioner for Patents
Washington, D.C. 20231

Raymond J. Lillie 1/19/01
Raymond J. Lillie, Esq. Date

Respectfully submitted,

Raymond J. Lillie
Raymond J. Lillie, Esq.
Reg. No. 31,778

CARELLA, BYRNE, BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN
Six Becker Farm Road
Roseland, New Jersey 07068
T: (973) 994-1700
F: (973) 994-1744

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**Patent Examining Operations**

Applicant(s): Burnside, et al

Serial No: 09/807,462

Art Unit: Not Assigned

Filed: April 11, 2001

Examiner: Not Assigned

Title: Oral Pulsed Dose Drug Delivery System

Attorney

Docket No.: 550750-185

Customer No.: 27162

REQUEST FOR EXTENSION OF TIME PURSUANT TO SECTION 1.136(A)

Commissioner for Patents

Washington, D.C. 20231

SIR:

Applicant hereby requests an extension of time to respond to the rejection pursuant to Section 1.136(a) for a period of four months with the following fee:

<input checked="" type="checkbox"/> One Month	<input checked="" type="checkbox"/> Small Entity \$ 55.00	<input type="checkbox"/> Other \$110.00
<input type="checkbox"/> Two Months	<input type="checkbox"/> Small Entity \$195.00	<input type="checkbox"/> Other \$390.00
<input type="checkbox"/> Three Months	<input type="checkbox"/> Small Entity \$445.00	<input type="checkbox"/> Other \$890.00
<input type="checkbox"/> Four Months	<input type="checkbox"/> Small Entity \$695.00	<input type="checkbox"/> Other \$1,390.00

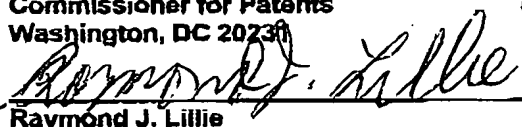
TOTAL AMOUNT: \$ 55.00

☒ Enclosed☐ Not Required

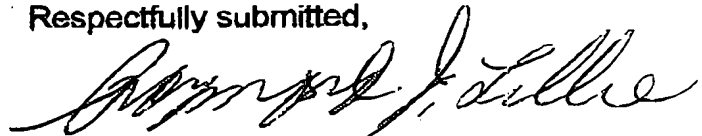
☒ Charge any additional fees to Deposit Account No. 03-0678
(One additional copy of this Notice enclosed herewith.)

EXPRESS MAIL CERTIFICATEDeposit Date: July 19, 2001

I hereby certify that this paper and the attachments hereto are being deposited today by "Express Mail to Addressee" on the date indicated above addressed to:

Commissioner for Patents
Washington, DC 20231
Raymond J. Lillie

Respectfully submitted,



Raymond J. Lillie, Esq.

Reg. No. 31,778

CARELLA, BYRNE, BAIN, GILFILLAN,
CECCHI, STEWART & OLSTEIN

6 Becker Farm Road

Roseland, NJ 07068

Tel. No.: (973) 994-1700

Fax No.: (973) 994-1744



U.S. APPLICATION NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/807462	BURNSIDE	B 550750 - 135
RAYMOND J LILLIE CARELLA BYRNE BAIN GILFILLAN CECCHI STEWART & OLSTEIN 6 BECKER FARM ROAD ROSELAND, NJ 07068		INTERNATIONAL APPLICATION NO. PCT/US98/24554
1A FILING DATE 20 OCT 99		PRIORITY DATE 21 OCT 98

DATE MAILED 07 MAY 2001

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/OS)

1. The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as ☐ a Designated Office (37 CFR 1.494) ☒ an Elected Office (37 CFR 1.495):

- ☒ U.S. Basic National Fee. ☒ Indication of Small Entity Status
☒ Copy of the international application. ☐ Translation of the international application into English
☒ Oath or Declaration of inventor(s). ☐ Translation of Article 19 amendments into English
☐ Copy of Article 19 amendments. ☐ Other.
☐ Priority Document.
☒ The International Preliminary Examination Report in English and its Annexes, if any.
☐ Translation of Annexes to the International Preliminary Examination Report into English.

2. ☒ Applicant has requested early processing under 35 U.S.C. 371(f) but has not filed the following indicated items and/or the indicated items in paragraph 3 below. The Basic National Fee and the copy of the international application must be filed prior to 20 or 30 months from the priority date to avoid abandonment.

- ☐ U.S. Basic National Fee ☐ Copy of the international application.

3. The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- ☐ a. Translation of the application into English. A processing fee will be required if submitted later than the appropriate 20 or 30 months from the priority date.
☐ The current translation is defective for the reasons indicated on the attached Notice of Defective Translation.
☐ b. Processing fee for providing the translation of the application and/or the Annexes later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(f)).
☐ c. Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), properly identifying the application (preferably by the International application number and international filing date). A surcharge will be required if submitted later than the appropriate 20 or 30 months from the priority date.
☒ The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) for the reasons indicated on the attached PCT/DO/EO/917.
☒ d. Surcharge for providing the oath or declaration later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(e)).

4. Additional claim fees of \$_____ as a ☐ large entity ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due (37 CFR 1.492(g)). See attached PTO-875.

5. ☐ Applicant has not submitted the required sequence listing pursuant to 37 CFR 1.821-1.825. See attached PCT/DO/EO/920.

ALL OF THE ITEMS SET FORTH IN 3(a)-3(d), 4 AND 5 ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 20 OR 30 MONTHS (whichever 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

6. If box 3a or 3c is checked, a translation of the Annexes **MUST** be submitted no later than the time period set above or the Annexes will be cancelled. A processing fee will be required if submitted later than 20 or 30 months from the priority date.
 7. ☐ The Article 19 amendments are cancelled since a translation was not provided by the appropriate 20 (37 CFR 1.494(d)) or 30 (37 CFR 1.495(d)) months from the priority date.

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in this heading and include the U.S. application no. shown above. (37 CFR 1.5)

A copy of this notice MUST be returned with this response.

- Enclosed ☒ PCT/DO/EO/917 ☐ Notice of Defective Translation
☐ PTO-875 ☐ PCT/DO/EO/920

Karen Williams

FORM PCT/DO/EO/905 (March 2001)

Telephone 703-305-3688